

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on February 20, 2012.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 15 days before the close of the written comment period.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 4052 and 4052.3 of the Business and Professions Code, the Board of Pharmacy is proposing to amend Section 1746 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board of Pharmacy ("Board") proposes to amend Section 1746 of Division 17 of Title 16 of the California Code of Regulations ("CCR") for the purpose of revising the protocol utilized by pharmacists to furnish emergency contraception (EC) drug therapy pursuant to the standardized protocol developed and approved by both the Medical Board of California (MBC) and the California State Board of Pharmacy (Board).

Existing law at Section 4052(a)(8) of the Business and Professions Code authorizes a pharmacist to furnish EC drug therapy as authorized by Section 4052.3 of the Business and Professions Code. Section 4052.3(a)(2) specifies that a pharmacist may furnish EC drug therapy in accordance with a standardized protocol developed and approved by both the MBC and the Board. Also, the development of the EC protocol by the Board must be made "in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized protocol is specified at Title 16 Section 1746 CCR.

The protocol specified in this proposal was first adopted in 2004. Since that time, there have been changes in the availability of emergency contraception medicine and the manufacturers

who produce the medication. It was also discovered that there is a typographical error in the board's current regulation that requires correction (mcg instead of mg).

In 2011, the Board's Executive Officer began working with a California Pharmacists Association representative (a women's health specialist pharmacist) and two representatives of the American College of Obstetricians and Gynecologists to develop and finalize a protocol which would reflect the changes in medicine and manufacturing for EC. The resulting draft was considered and approved by the Medical Board of California at its July 2011 meeting. The Executive Officer provided updates to the Board's Communication and Public Education Committee on January 10, 2011 and on September 26, 2011. In September 2011, the committee recommended that the Board initiate a rulemaking to repeal and to amend 16 CCR Section 1746 to be consistent with the proposed draft and update of the EC Protocol that was approved by the Medical Board in July 2011. This recommendation was adopted by the Board at its October 18, 2011 board meeting.

Existing regulation at 16 CCR § 1746(a) specifies that a pharmacist furnishing EC shall follow the protocol specified in subdivision (b) of the section.

This proposal updates a statutory reference specified in subdivision (a).

Existing regulation at 16 CCR § 1746(b) specifies the protocol to be used by pharmacists furnishing EC, to include authoritative references, purpose, information that must be communicated to the patient, training, documentation and other requirements. Paragraph (11) specifies a table of oral contraceptives used for EC; and paragraph (12) specifies a table of anti-nausea treatment options for use with EC.

The proposed amendments to Section 1746(b) would update statutory references within the section; would update the information that is to be communicated to the patient when the patient requests EC; would correct a typographical error; and would revise and recast the table of dedicated approved products for EC specified at paragraph (11). The board believes its proposal would benefit consumers and pharmacies, and would also benefit the public health and safety in that an updated chart of EC drug therapy will be available to pharmacies and consumers. The board also believes that the proposed regulation promotes fairness to FDA approved drug manufacturers, in that the table of dedicated approved products for EC specifies that generic equivalent drug products may be furnished to a consumer requesting EC drug therapy; this could also benefit pharmacies by having additional drug manufacturers from which to purchase drug products that are furnished in accordance with the regulation. The board does not regulate prices for which pharmacies charge consumers for dispensed drug products; however, the board believes it is possible that the list of dedicated approved products for EC, as well as generic equivalent products, may give a pharmacy and a consumer options in what dedicated approved products for EC is furnished in accordance with the protocol.

Based on an initial evaluation, the board does not believe that the proposed regulation is inconsistent or incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose a new requirement on a pharmacy licensed with the Board of Pharmacy; rather, it proposes to modify the table of dedicated approved products used for emergency contraception and make other specified changes to the existing protocol, as jointly approved by the Medical Board and the Board of Pharmacy.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The agency is not aware of any cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action. This determination is based on the fact that a pharmacist is currently authorized to furnish emergency contraception pursuant to a protocol jointly approved by the Medical Board and the Board of Pharmacy.

Effect on Housing Costs: None

ECONOMIC IMPACT ANALYSIS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose a new requirement on a pharmacy licensed with the Board of Pharmacy; rather, it proposes to modify the table of dedicated approved products used for emergency contraception and make other specified changes to the existing protocol, as jointly approved by the Medical Board and the Board of Pharmacy.

As part of its Economic Impact Analysis, the board has determined that its proposal will not affect the ability of California businesses to compete with other states by making it more costly to produce goods or services, that it will not create or eliminate jobs or occupations, and the proposal will not affect the ability of California businesses to compete with other states by making it more costly to produce goods or services. The board's proposal does not impact multiple industries.

Small Businesses: The board's proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are "small businesses" as defined in Government Code Section 11342.610.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs, businesses or the expansion of businesses in the State of California.

Occupations/Businesses Impacted: The Board of Pharmacy has made an initial determination that this regulatory proposal will impact pharmacists and pharmacies. As of October 2011, the board had approximately 37,743 pharmacists (individuals) with current licenses issued by the board. Also, as of October 2011, the board had approximately 6,900 pharmacies (sites) with current licenses issued by the board.

Reporting Requirements: None

Comparable Federal Regulations: None

Benefits: Business and Professions Code section 4005 states that "the board may adopt rules and regulations....pertaining to the practice of pharmacy...." Further, Business and Professions Code 4001.1 states that the "protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount." The purpose of the proposed regulatory changes is to ensure that the drug products specified in the board's emergency contraception drug therapy protocol specifies current drug information. Since the establishment of Section 1746 in 2004, there have been changes to drugs utilized for emergency contraception as well as the manufacturers that produce these drugs. Both pharmacists and patients will benefit from having an EC protocol available that has updated drug therapies.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site <http://www.pharmacy.ca.gov>.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
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E-Mail Address:	Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
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Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.